URGENT DEVICE FIELD CORRECTION

Symbiq™ One Channel Infuser – List Number 16026
Symbiq™ Two Channel Infuser – List Number 16027

Malfunction S205: Backup Battery Failure

February 8th, 2013

Dear Healthcare Professional:

Hospira Healthcare Corporation is issuing this letter because we have received reports of Malfunction S205 Backup Battery Failure alarms in some Symbiq v3.13 pumps. This error is related to an installation issue with components on some of the Power Supplier Controller (PSC) Boards. In those cases where components on the PSC board were not installed correctly, the backup battery (coin cell) discharges and cannot be recharged. Devices experiencing this issue will display a visual warning, S205 Malfunction, and an audible alarm will be triggered. The coin cell battery powers the backup buzzer (alarm) and will need to be charged or replaced. The visual warning will be displayed on the user interface screen until the issue is corrected. There are no other situations or events that will cause a S205 alarm to be displayed

It is highly unlikely that this issue would cause any harm to a patient. The S205 alarm does not stop the pump, or interfere with the infusion. The coin cell battery is not used to power the device during infusion.

The coin cell battery is only used to power the device's secondary buzzer to inform the user that the power level (no/low AC power or depleted main battery) has dropped below the level required to operate the infuser.

Recommended actions:

If an S205 alarm is observed perform the following steps to determine if it is caused by this issue:

1. Charge the backup battery for 20 hours by plugging the pump into an AC power outlet as defined in the Symbiq Technical Service Manual.

2. At the completion of the charging cycle, perform a PVT test. If the test indicates that the S205 failure is still present, the device may be impacted by this issue.

3. Although this issue is unlikely to cause any harm to a patient, Hospira recommends that your facility remove the device from service and contact Hospira Canadian Service Center at 1-866-488-6088 Option 5 to report the issue and to arrange to have your device repaired.

Hospira Healthcare Corporation
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Please complete the attached reply form and return it via fax to the number on the form, *even if you do not currently have a Symbiq Infuser. If you have further distributed the Symbiq Infusers, please notify your accounts who may have received these infusers from you and ask them to complete the reply form.*

For further inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Canadian Service Center	1-866-488-6088 Option 5, CanadaPumpSupport@hospira.com	To report adverse events or product complaints
Hospira Clinical Support	1-866-488-6088 Option 4, mail-ClinSupport@hospira.com	For Clinical Assistance

Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and we regret any inconvenience this action may cause.

Sincerely,

Rania Al-Ammar
Regional Director, Commercial Quality